

REMARKS

The Final Office Action of October 2, 2001 presents the Examination of claims 44-68. These claims are all canceled and replaced with new claims 69-108. This manner of amendment was chosen because the previous large number of amendments had confused the structure of the claims and left several redundant claims in the application. For example, the prior claim 44 had been amended to recite a gene expression system comprising "an operon". On the other hand, claim 68 recited a "co-transcribed operon", which is redundant as co-transcription of the genes of an operon is one of the features that defines an operon. Also, pending claims 59 and 60 indicated that component genes were arranged in an operon. The newly presented claims 69-108 have a structure that is more understandable.

The new claims also better describe the features of the invention that distinguish it from the prior art. For example, one aspect of the invention that distinguishes it from the prior art of record is that the IF gene, or functional analog thereof, is not transcribed from the same promoter that drives expression of the SakK and SakR genes. On the other hand, in the cloned gene clusters described in the prior art of record, a gene analogous to the IF gene is transcribed together with a gene analogous to the SakK gene and with a gene analogous the SakR

gene as part of an operon. Thus all three of the genes are transcribed from the same promoter.

Support for the new claims

Most of the new dependent claims merely re-present a previously pending claim.

The various arrangements of the genes and promoters recited in the claims, especially the separation of the transcription of the regulatory IF, SakK and SakR genes from transcription of the desired gene, are supported by, for example, page 7, line 24 to page 8, line 19 of the specification.

The recitation of properties (i) to (iv) of the expression product of the IF gene or functional analog thereof is supported at, for example, Example 3 at page 15, page 16, lines 21-23 (length and inducing functions) and page 4, page 5, line 9 and page 7, line 27 ("not a lantibiotic").

The functions of the IF gene product, which define "functional analogs" of the IF gene and its expression product are described at, e.g. page 18, lines 29-31, page 20, lines 1-16, page 16, lines 3-8 and page 27, lines 4-7. Furthermore, structural variants of the IF gene expression product are described at, e.g., page 15 lines 3-4, page 15, line 36 to page 16, line 2.

The functions of the SakK gene product, which define "functional analogs" of the SakK gene and gene product are described at, e.g., page 7, lines 21-29, page 9, lines 1-3 and the references cited there, page 10, lines 29-30, page 19, lines 4-11 and in Figure 5 and the description thereof at page 7. The *PlnB* gene product is a species of "functional analog" of the SakK gene product (see, p. 7, line 22 and Huhne et al., *Microbiology* 142:1437-1448 (1996) (copy attached)).

The functions of the SakR gene product, which define "functional analogs" of the SakR gene and its product are described at, e.g., page 7, lines 21-29, page 9, lines 4-7 and the references cited there, page 10, lines 30-33, page 19, lines 4-11 and in Figure 5 and the description thereof at page 7. The *PlnC* or *PlnD* gene product is a species of "functional analog" of the SakR gene product (see, page 7, line 22 and Huhne et al., *Microbiology* 142:1437-1448 (1996) (copy attached)).

Gene expression systems comprising DNA encoding SakK and SakR and an added peptide are described e.g. at page 5, line 14 to page 6, line 6 and page 7, lines 23-26.

The kit claims, reciting host cells and vector constructs having different arrangements of the elements of the gene expression system of the invention, are supported by disclosure at, e.g., page 7, line 35 to page 8, line 21.

Rejections under 35 U.S.C. § 112, second paragraph

Prior claim 64 was rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness in reading upon a system having gene elements duplicated in both a vector and a host cell. Applicants submit that such an arrangement is neither confusing nor inoperative. The present corresponding claims 89 and 90 recite that the vector element of the system does not include IF-K-R regulatory genes resident in the chromosome of the host cell.

Prior claims 44-65, 67 and 68 were rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness in the recitation of the terms "functional analog" and "similar". This rejection is respectfully traversed as it might be applied to the pending claims. Applicants submit that the rejection should not be applied to the pending claims.

As to "functional analogs", the Examiner takes a position that there is no "art-accepted" definition of the term. Terms in the claims are interpreted first in view of what is actually written in the claims. If the terms of the claims are not clear of themselves, then one looks to the specification for specific definition or other evidence of meaning. If the specification does not provide the answer, then the prosecution history is consulted. Only if these intrinsic sources of meaning fail to clarify the claim terms does one look to extrinsic evidence of

meaning of the claim terms, such as a dictionary or other source of understanding of a term. *O. I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1581, 42 U.S.P.Q.2d 1777, 1780 (Fed. Cir. 1997).

Applicants submit that there need not be any art-accepted definition of the term for the term to be definite. First, the claims themselves describe the function for the various recited genes which must be retained by the "functional analogs thereof." That is, the product of the IF gene, or functional analogue thereof

- (i) induces the production of bacteriocins by a lactic acid bacterium,
- (ii) is not a lantibiotic,
- (iii) induces the expression of genes regulating bacteriocin production in said lactic acid bacterium, and
- (iv) activates the expression product of the SakK gene, or functional analogue thereof.

Furthermore, the activated expression product of the SakK gene, or functional analogue thereof, activates the expression product of the SakR gene, or functional analogue thereof. Finally, the activated expression product of the SakR gene, or functional analogue thereof, induces the first promoter of the gene of interest, thereby causing expression of the gene of interest. If this is not clear to the Examiner, then she may turn to the specification to learn what is intended by the term "functional

analog". The specification, as explained above, describes functions of the various recited gene elements. One of ordinary skill in the art would understand that these functions define what constitutes a "functional analog" of the recited element.

The Examiner further states that the rejected claims are indefinite due to the recitation that a functional analog of the IF gene product is, "... similar to peptides that are naturally produced by lactic acid bacteria." The Examiner takes a position that "similar" is indefinite as it does not describe any degree of structural resemblance. Applicants have omitted the term "similar" from the present claims, thus obviating this ground of rejection.

For the reasons explained above, the instant rejection of claims 44-65, 67 and 68 under 35 U.S.C. § 112, second paragraph, should not be applied to the present claims.

Rejection under 35 U.S.C. § 112, first paragraph

*Written Description*

Claims 44-65, 67 and 68 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description of the claimed invention. This rejection is respectfully traversed as it might be applied to the present claims. Applicants submit that the rejection should not be applied to the pending claims.

The Examiner summarily indicates that the basis for the rejection is the same as previously explained. There seem to be three bases for the rejection. The Examiner first indicates the claims recite, "an inducible promoter" or "a promoter". The Examiner suggests that these terms are not described in the application because the specification does not describe any promoter induced by the SakR gene product "per se". This is simply incorrect. At page 10, lines 30-36, for example, the specification states,

The product of R acts on the promoter elements depicted in Fig. 4 either directly, as an activator, or indirectly, by binding as a repressor that until [sic] the moment of induction prevents transcription.

This passage explicitly states that the R gene product acts to induce a promoter, which promoter is further described by Figure 4 of the application.

Furthermore, the claims do not recite that the R gene product "per se" induces the promoter. Rather, the claims recite that the R gene product is activated by the SakK gene product before it induces transcription from the inducible promoter element. This aspect of the invention is commensurate with the disclosure at page 10, lines 30-36 and further supported by the disclosure of Figure 5.

Second, the Examiner also indicates that the specification fails to describe the detailed mechanism of the activation process. There is no requirement imposed by 35 U.S.C. § 112 that the detailed mechanism by which an invention functions be described in the specification. *Congoleum Industries, Inc. v. Armstrong Cork Company*, 173 U.S.P.Q. 147 (E.D. Pa 1972), citing *Intermountain Research & Eng. Co. v. Hercules, Inc.*, 160 U.S.P.Q. 515 (9th Cir. 1969); *Electric Storage Battery Co. v. Shimadzu*, 51 U.S.P.Q. 427 (3d Cir. 1941). Thus, this basis for the rejection is entirely groundless.

Third, the Examiner states that the prior claims 44 and "claims dependent thereon",

... encompass a genus of a first inducible promoter, an IF gene, a SakK gene, a SakR gene, the expression products of said genes and functional analogs thereof.

The Examiner appears to have two objections to the scope of the generic claims.

As the first objection, the Examiner states that Applicants teach that references to the group IF, K and R (or analogs thereof) should be interpreted as reference to these three genes "and such a possible extra gene if it would appear to exist." The Examiner cites page 21, lines 17-20 and the sentence bridging pages 10 and 11 for this proposition and takes a

position that Applicants have failed to describe an essential element of the invention. (See, the Examiner's comment in the sentence bridging pp. 4-5 of the Office Action.) First, the "extra gene" is not an element of the claims and thus need not be described. Second, Applicants submit that the Examiner is reading the specification rather selectively. For example, at page 7, lines 23-28, the specification teaches that the IF-K-R gene cluster can be induced at will by addition of the IF peptide. Also, at page 10, lines 33-36, the specification expressly states that the gene products of the IF, K and R genes are sufficient to induce transcription from the relevant promoter. Thus, this aspect of the invention is well-described in the specification.

As the second objection, the Examiner states that the scope of the claims encompasses numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The Examiner takes a position that no common structural attributes that identify members of the genus are described and therefore the specification fails to adequately support claims 44-65.

As a threshold matter, not all of the claims have the scope the Examiner suggests. For instance, new claims 70 and 95 do not recite "functional analogs". Claims 71, 72, 96 and 97 recite a particular amino acid sequence as the structurally

defining member of the genus with respect to the IF gene product and thus as a common defining element of that sub-generic claim. In claim 77, the "functional analogs" are recited as *PlnA*, *PlnB*, *PlnC* and *PlnD* genes of a lactic acid bacterium. Applicants submit that the instant rejection should not be applied to at least these more limited claims.

Furthermore, claim 86 recites structure of the promoter that is activated by the regulatory genes. Although there is no structural limitation on the "functional analogs" imposed by this limitation, activation of this promoter by the regulatory gene cascade is a physical chemical property that serves to define the genus of claim 69.

Applicants further note the Examiner's position that the representative number of species of each of the IF, K and R genes or functional analogs thereof is only one. This is also incorrect. The specification states (e.g. at page 7, lines 21-23) that the *PlnABCD* gene complex of *L. plantarum* C11 constitutes a functional analog of the IF-K-R complex the present invention. Thus, there are at least two species of each gene that is recited in the claims described in the application. Furthermore, as described above, there are additional structures for the IF peptide disclosed in the application (Note SEQ ID NOS. 1 and 2 and the description at page 20, lines 10-12 about

truncated peptides) and thus at least three species of this peptide are described.

Furthermore, it is not required that structural features of an invention provide the common characteristic that defines the genus. The Written Description Guidelines of January 5, 2001 (66 F.R. 1099) state that:

[P]ossession may be shown, *inter alia*, by describing actual reduction to practice of the invention. ...

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e. complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between structure and function, or some combination of such characteristics. (Emphasis added.)

See, 66 F.R. 1099 at 1105, col. 3, lines 50-51 and at 1106, col. 1, lines 22-33.

With regard to description of a species, description of function alone can suffice as description adequate to evidence possession of the invention. (See, 66 F.R. 1099, 1106 at col. 2, line 36.) Thus, the Examiner's assertion at page 6, lines 7-8 of the Office Action that, "description by function only does

not provide adequate written description of a compound" is incorrect.

The present specification describes the present invention very well in terms of its functional characteristics, and these characteristics are recited in the claims. Furthermore, complete structures of the IF gene product are recited the specification, and the relevant portions of the promoters activated by the expression system are structurally characterized (Fig. 4). The specification discloses that the activation of the system is dependent upon inclusion of three particular gene products, SakK, SakR and IF. The specification discloses at least two species for each of these elements. Still further, the specification discloses that additional species of the IF, K and R genes can be found in other lactic acid bacteria and describes an assay (Example 1) that can be used to determine if a particular strain expresses the relevant genes. The specification also discloses an assay that can be used to determine if any particular isolated SakK, SakR or IF gene is functional in the invention (Examples 2 and 3).

Applicants submit that the above disclosure of the specification provides adequate evidence that Applicants were in possession of the claimed invention at the time the application was filed. Accordingly, the instant rejection of claims 44-68 under 35 U.S.C. § 112, first paragraph, for lack of adequate

written description, should not be applied to the present claims.

### *Enablement*

Claims 44, 46, 48-62, 64, 65, 67 and 68 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enabling disclosure of the claimed invention. Applicant submit that this rejection should not be applied to the presently pending claims.

As a threshold matter, the Examiner fails to establish a proper *prima facie* case for lack of enablement. The Examiner merely states in summary fashion that the specification does not reasonably provide enablement for an expression system comprising functional analogs of [IF, SakK and SakR genes and their products] nor of a method for their use.

Once again, the issue in determining whether a specification enables a claimed invention is whether undue experimentation is required to practice the invention throughout the scope of the claims. The amount of experimentation is not determinative, but is only one factor to consider. The nature of the invention, the breadth of the claims, the guidance provided by the specification, the level of skill in the art, the presence or absence of working examples, the prior knowledge

of the skilled artisan and the predictability of the art must all be considered. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

In the present instance, the invention described in the rejected claims lies in a gene expression system comprising as its recited elements three genes and a promoter from which transcription of a desired nucleic acid is effected, wherein the products of the three genes activate one another, finally activating the promoter. The Examiner's objection lies in the breadth of the claims, which recite "functional analogs" of the IF, SakK and SakR genes expressly described in the application.

The level of skill in the art of biotechnology is generally accepted to be very high. Most practitioners in the field hold advanced degrees; very many hold doctoral degrees and have several years of laboratory experience.

The knowledge in the art of "two-component" regulatory systems, of which the present invention is an example, is fairly high, as evidenced by the citation by the Examiner of four references said to anticipate the present invention. For example, there was extensive knowledge about how the genes regulating nisin expression function at the time the invention was made. Practitioners implementing further embodiments of the present invention, beyond those specifically exemplified in the present specification, may draw upon that knowledge.

The guidance provided by the specification is extensive. That guidance includes a description of an assay for determining whether a given bacterial type expresses a set of genes providing a regulatory phenotype similar to that provided by the IF-K-R complex (Example 1). This assay was applied to characterize and isolate the IF-K-R complex from *Lactobacillus sake* and also a second complex of genes from *Lactobacillus plantarum* C11. Thus, there are two working examples of the invention provided by the specification. Assays for function of IF peptides are also described (Examples 2 and 4). The specification further informs the practitioner that functional variants are likely to be found in bacteria of the genus *Lactobacillus*. (See, page 10, lines 1-5 and line 18.) Thus, the skilled artisan is provided with guidance as to where to start looking for functional variants if IF, SakK and SakR genes. Example 6 shows that this guidance is effective.

The Examiner's primary point seems to be that the art is unpredictable. Applicants have previously acknowledged that is the case, but again, the sort of unpredictability asserted by the Examiner is not determinative.

Applicants agree that, *a priori* one of skill cannot tell if a set of genes will have the properties described for "functional analogs" of the IF, SakK and SakR genes. In particular, if they would function to control a promoter upon

activation of a cascade started by an "IF" peptide is not apparent merely by examination of a gene sequence. However, examination of the organization of a set of genes can provide helpful clues. See, page 10, lines 1-5 of the specification. Furthermore, the specification informs the skilled artisan how to determine whether a given set of genes represents a functional analog of the IF, SakK and SakR genes and also provides guidance as to where to begin to search for such functional analogs.

The Court of Appeals for the Federal Circuit, in the *Wands* case, expressly held that experimentation considered typical in an art is not undue. In *Wands*, a hybridoma invention claimed in broad, functional terms was considered well-enabled, despite the facts that (1) only 2.8% of hybridomas screened produced a functional antibody and (2) that only 2 of 10 screening experiments succeeded at all.

The skilled artisan in molecular biology, especially in the art of gene expression, expects to have to perform various screening experiments to isolate functional variants of already known genes and their products. Such screening is manifestly not undue experimentation under the holding of *In re Wands*.

Applicants submit that, in view of the above considerations, it is not undue experimentation to practice the

invention as claimed. Accordingly the instant rejection should not be applied to the present claims.

Applicants further note that evidence of record, in particular Exhibits 1-4 filed with and explained in Applicants response of October 16, 2000, shows that "functional analogs" of the IF, SakK and SakR genes and their products can be isolated following the teachings of the specification. The Examiner has never addressed this evidence or Applicants' explanation of it.

Applicants have also noted the Examiner's comment at page 6, lines 14-15 of the Office Action that, "the claims are not directed to structurally homologous genes from *Lactobacillus*." New claim 77 recites that the functional analogs are from a lactic acid bacterium and thus at least this claim should be considered free of this rejection.

For all of the above reasons, Applicants submit that the present rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement of the invention, should not be applied to the present claims.

#### Rejections over prior art

Claims 44-67 stand rejected under 35 U.S.C. § 102(b) as anticipated by any one of Diep et al. (1994), Tichaczek et al., Axelsson et al. or Venema et al. These rejections are all

traversed. Applicants submit that they should not be applied against the present claims.

Applicants have previously argued that none of the applied references disclose a property of the presently-claimed gene expression system that the SakR gene product is activated by the SakK gene product that is in turn activated by the IF peptide.

The Examiner takes a position that the cascade of activation asserted by Applicants to establish novelty is an "inherent" property of the system. Whether or not this is true, the Examiner should first note that none of the references describe a gene expression system in which a selected polynucleotide is placed under control of a promoter that is regulated by an activation cascade that begins with the product of an IF gene or functional analog thereof. Thus, none of the cited references describe the invention and all of the standing rejections for lack of novelty of the invention are improper. Furthermore, whether correctly described in the references or not, a property of all of the genetic systems described in the cited references (i.e. *pln* (Diep), *sak* (Tichaczek, Axelsson), *ped* (Venema)) is that all of the genes are transcribed as a single operon from a single promoter. On the other hand, in all of the present claims directed to a gene expression system, or host cells comprising it, at least the IF gene encoding the inducer is in an arrangement such that it is no longer part of any operon in

which the *SakK* and/or *SakR* genes are also transcribed. In some claims, the *IF* gene is absent or an *IF* peptide is recited.

Axelsson does describe separation of *sapR* and *sapK* from "Orf4". However, Axelsson's paper fails to describe that "Orf4" has any function and in any event, Axelsson's annotation of the transcription pattern is incorrect. The correct organization of the typical cluster of *IF*, *K* and *R* genes in a single operon is shown in Figure 1 of the present application (see also page 8, lines 23-24). Thus, Axelsson does not describe the present invention and the anticipation rejection over this reference must be withdrawn.

Tichaczek describes only the *SakP* gene. As shown in Figure 1 of the present application, this gene is part of an operon that is distinct from the *SakIFKR* operon. "OrfY" is not particularly characterized, other than as to the molecular weight of the encoded protein. From its location downstream of the *SakP* gene, this would appear to be the *I* (not "IF") gene product related to immunity to sakacin (see page 9, line 13 of the present specification). "OrfX" is located upstream of *SakP* and thus might be the *SakR* gene of the present invention. However, Tichaczek only describes a small piece of the actual "OrfX" gene. Furthermore, Tichaczek does not ascribe any function to "OrfX" and thus does not appreciate the regulatory cascade of the present invention. Thus, Tichaczek does not

anticipate the present invention. Tichaczek cannot suggest the present invention, as at least two genes of the present invention are not described, nor is their regulatory interrelationship.

The Venema reference (*Molecular Microbiology* 17:515-522 (1995)) is entirely irrelevant to the present invention. Venema et al. describe a pediocin operon consisting of the *PedABCD* genes. The naming of these genes is similar to that of the plantaricin genes, *PlnABCD*, which are functional analogs of the *SakIFKR* genes of the present invention. However, the similarity of the *PedABCD* genes stops at their names.

Careful reading of the Venema paper will show that the functions of the *PedB*, *PedC* and *PedD* genes are entirely different from those of the *SakIF*, *SakK* and *SakR* genes (and so also from *PlnB*, *PlnC* and *PlnD*). *PedB* mediates immunity of the host cell to the pediocin bacteriocin (encoded by *PedA*). Note lines 19-20 in column 1 on page 519. *PedC* is involved in channel formation during secretion of the pediocin peptide. Note the last three lines in column 1 on page 519. *PedD* is involved in maturation of the pediocin bacteriocin during its secretion. Note line 23 in column 2 on page 517 and lines 11-13 in column 2 on page 519.

Diep et al. describe the *PlnABCD* operon, described in the instant specification as a functional analog of the *SakIFKR*

genes. However, Diep et al. do not anticipate the present invention, nor in any way suggest it.

First, Diep et al. describe *PlnA*, *PlnB*, *PlnC* and *PlnD* as being transcribed together in a single operon, and thus from a common promoter. See, Figure 4 of the reference. Though not realized by Diep et al., *PlnA* encodes a functional analog of IF, in that *PlnA* performs an inducer function. On the other hand, the present claims recite that the IF gene is transcribed from a promoter different from (at least in being a second one, though also possibly structurally and functionally different as described in dependent claims) either or both of the promoters from which the SakK gene and the SakR gene (or their functional analogs) are transcribed.

The claims also describe an inducing function of the IF gene product, or functional analogs thereof. Alternative embodiments of the invention recite a gene expression system in which the peptide encoded by IF is added as a polypeptide. Diep et al. describe only the lytic function of plantarcin (e.g. the caption to Figure 4 of the reference). The regulatory role of the bacteriocin (encoded by *PlnA*), if any, is unknown. Thus Diep et al. cannot appreciate and therefore do not anticipate that an IF peptide, or functional analog thereof, can be added to a system to induce expression of a desired gene that is

coupled to a promoter of a *SakIFKR* gene complex (or functionally similar promoter).

In fact, even as late as 1996, the inducing function of IF was unknown. Applicants note again the Huhne et al. paper attached. Huhne et al. was published some time after January of 1996, at least two months after the priority date of the present application. At the end of the first paragraph in column 1 on page 1446, the authors expressly state that, "nothing is known about the nature of the signal that triggers [sakacin P] production."

Furthermore, the peptide encoded by ORFI as described by Huhne et al. is indicated as "not homologous to any known peptide in the databases." (Page 1447, col. 1, line 18.) Therefore, even as late as early 1996, the inducing function of IF was not known in the prior art.

Applicants have also argued that none of the cited references correctly describe the promoter recited in, e.g. the present claims 86, 107 and 108. The Examiner appears to also allege that the particular structure of the promoter is inherent in the gene complexes described in the references.

Applicants submit that there is no description in the cited references that points the skilled artisan to the repeat structure recited in claims 86, 107 and 108, and especially no disclosure that points the skilled artisan to the particular

portions of sequence recited in claims 86 and 108. Accordingly, the cited references cannot properly ground a rejection for anticipation. See, *In re Rushig*, 145 USPQ 274 (CCPA 1965); *In re Petering*, 133 USPQ 275 (CCPA 1962).

For all of the above reasons, the instant rejection should be found novel over each of Diep et al. (1994), Tichaczek et al., Axelsson et al. and Venema et al. and the instant rejections should not be applied to the pending claims.

Furthermore, there is no suggestion in any of the references that their teachings should be modified to produce the invention as claimed. Thus, no combination of the references can properly render the present invention *prima facie* obvious and the Examiner should not simply reply with an obviousness rejection over the same references.

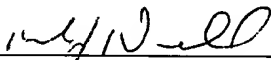
Applicants submit that the present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims is respectfully requested.

If the Examiner has any questions concerning this application, the Examiner is requested to contact Mark J. Nuell, Reg. No. 36,623 at the telephone number of (703) 205-8000.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of \$200.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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